ISPOR 6TH LATIN AMERICA CONFERENCE
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DESAFIOS NOS SISTEMAS DE SAÚDE DA AMÉRICA LATINA:

QUAIS EVIDÊNCIAS DE MUNDO REAL SÃO NECESSÁRIAS PARA ESTIMAR VALOR DE EQUIPAMENTOS MÉDICO-ASSISTENCIAIS E TESTES DIAGNÓSTICOS EM UM PROCESSO DE AVALIAÇÃO DE TECNOLOGIAS EM SAÚDE?

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Topics

- Medical devices challenges
- Value Assessment
- Conclusion

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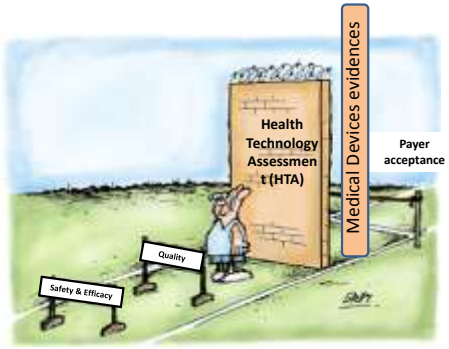
Medical Devices barriers is it?



Devices versus Drugs

	Medical Devices	Drugs
Properties	Physical	Chemistry
Complications	Decrease with use	Increase with use
Life cycle	Rapid release	Long release
Feasibility of blinding or Placebo control	No	Yes
Investment in training	High	Low
Cost	High expenses	Risk concentrated in pre-Market
Adherence	Alto	Variable
Size of patient Population	Low	High
Realized patient protection	Low	High

Source: Adapted form Klie Leidy et al and from Faukner et al

The Devices results depend on....

Evaluate only the prices

Topics

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1. STEP
Stakeholders often have different, interests and incentives

- Integrate **viewpoints of patients, providers and others** before decisions are finalized

Payers: historically, want the least the expensive product that “fixes” the basic problem

Physicians: want to be the first to try a new technology

Patients: generally accept what the physician or payer deems appropriate

- Understand that devices often can be part of sophisticated patient care processes where operator expertise and the care setting can influence outcomes as much as the technology itself

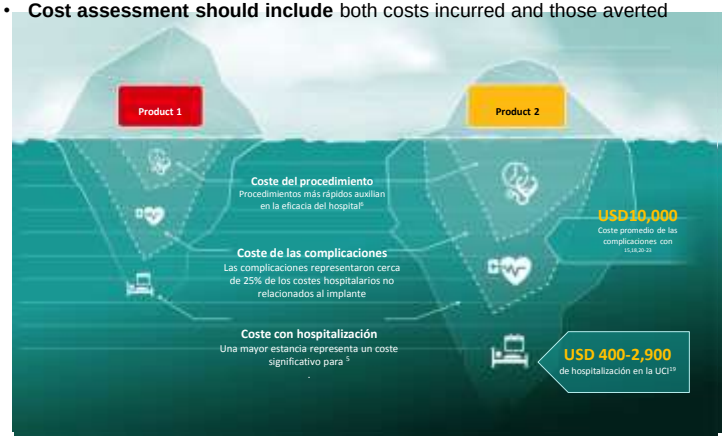
2.Step
Evaluate Epidemiological data….

- Be creative generate **parallel research** on external data sources
- Encourage **protocol development :** “right solution, right patient”
- Same patient characteristics?
  - Same implant local?
  - Operator learning curve?
- Same regulatory submission?
  - FDA / CE / ANVISA / INVIMA/ COFEPRIS...
- Size patient number?
  - 80 VS 1.000

3. Step
RWE and other data partnerships are creating new opportunities for value demonstration across lifecycle

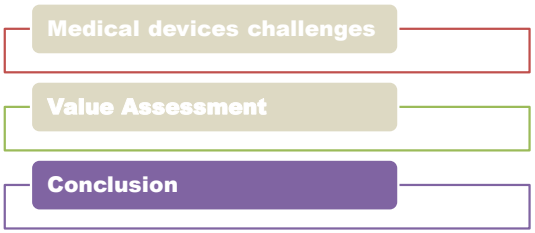
4.Step
Evidences impact in costs....

- **Cost assessment should include** both costs incurred and those averted



[6]Mehilli et al. EuroPCR 2015. Presentation [8]Arnold, et. al. (2014) [9]Gutmann et. al. (2014) [10]Chevreul et al. (2013) [11]Tan et. al. (2012)

Topics



Sumarize

- May **shorten the time** of a medical device **evaluation**
- May allow for the design of **clinical trials** that **may produce** required **outcomes for coverage** determinations **as RWD**
- Increase differentiation in the market
- **Evaluation** Clinical trial the methods and evidences level

Goals happen when we work together